Exhibit 12 K053427

Summary of Safety & Effectiveness

JAN 13 2006

1 December 2005

The ***Fresh, Dental Impression Material*** are designed for dental applications to define and reproduce the reproduce the structure of a patient's teeth and gums for producing crowns, bridges, occlusal and dental implant. This is a Class II material, having Regulation Number: 21 CFR part 872.3660 and **Product Code:** ELW.

This summary is submitted in behalf of:

Exacta Dental Products, Inc
44780 Macomb Industrial Dr.,
Clinton Township, MI 48036
Voice phone number-(800) 474-7665
Fax phone number- (800) 204 4430

This summary is submitted by:

Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, Connecticut, 06907
voice phone number (203) 329 2700)
fax phone number (203) 329 2345.

The ***Fresh, Dental Impression Material*** is **described** as a Class II , impression material that is used to reproduce the structure of a patient's teeth and gums for producing crowns, bridges, occlusal and dental implant.

The **scientific concept** on which this material is based is the principle that by mixing the base and catalyst components together the material is placed into an impression tray and inserted into the patient's mouth will cause the material to conform to the patient's dentition and when set will produce a highly accurate reproduction of the patient's teeth and occlusion.

The **intended use** of this material is for a trained dental to reproduce the structure of a patient's teeth and gums to make crowns, bridges, occlusal and dental implant impressions.

The "Indications for Use" for this material is intended for use with all crowns, bridges, occlusal and dental implant impression techniques to reproduce the structure of a patient's teeth and gums.

This is a *prescription only* material. The labeling, instructions and user operations are designed for health care professionals.

Exacta Dental Products, Inc has determined that the ***Fresh, Dental Impression Material*** are substantially equivalent to the performance of these predicate materials: K 052090, Splash Dental Impression Material .

Exhibit 12
Summary of Safety & Effectiveness

The ***Fresh, Dental Impression Material*** has benefited from design, development, testing and production procedures that have been certified to ISO 9001, ISO 14385 and the EU Declaration of Conformity for Medical Products

This material is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. ***Exacta Dental Products, Inc*** continues to search all appropriate sources for information relating to safety and effectiveness and maintains an *in-house* reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION:
I hereby certify this **Summary of Safety and Effectiveness** applies for the above indicated material.

Mr. John Pankuch
President
Exacta Dental Products, Inc
44780 Macomb Industrial Dr.,
Clinton Township, MI 48036
Voice (800) 474-7665
Fax (800) 204 4430

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

Exacta Dental Products, Incorporated
C/O Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, Connecticut 06907

Re: K053427
Trade/Device Name: Fresh™
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: December 01, 2005
Received: December 08, 2005

Dear Mr. Keen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

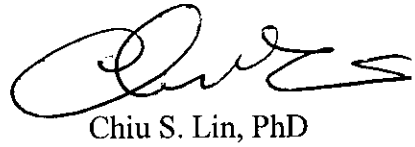
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 2
Indications for Use

510(K) Number (If known): K053427

Material Name: ***Fresh, Dental Impression Material***

Indication For Use:
Fresh, Dental Impression Material is intended for use with all crowns, bridges, occlusal and dental implant impression techniques to reproduce the structure of a patient's teeth and gums.

Prescription Use __XXX__ **OR** **Over - The - Counter Use** _____
(Part 21 CFR 801.109) **(21 CFR 807 Subpart C)**

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K053427